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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,049	11/28/2001	Jennifer L. Policky	PI-0072 USN	9619

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,049	POLICKY ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 13 15-17 19 22 26-28* is/are pending in the application.

4a) Of the above claim(s) *8 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 9, 11,13,15-17,19, 22 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1 to 11, 13, 15 to 17, 19, 22 and 26 to 28 are pending in the instant application.

2) The preliminary amendment canceling original claims 12, 14, 18, 20, 21, 23 to 25 and 29 to 56, that was filed on 28 November of 2002 as part of the form PTO-1390, is acknowledged and has been entered.

3) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See lines 1 and 5 on page 17, line 7 on page 58, and line 29 on page 66. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01(p), which states that:

> "When a patent application with embedded hyperlinks and/or other forms of browser-executable code issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial web site. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. If hyperlinks and/or other forms of browser-executable code are embedded in the text of the patent application, examiners should object to the specification and indicate to applicants that the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion."

Correction is required.

4) Claims 8 and 10, as well as claims 1 to 7, 9, 11, 13, 15 to 17, 19, 22 and 26 to 28, in so far as they relate to an amino acid sequence other than SEQ ID NO:1, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in correspondence filed 18 October of 2004. The traversal is on the ground(s) that the restriction requirement is inconsistent with the stated restriction policy presented in M.P.E.P. 803.04. Applicant is advised that this policy was discontinued several years ago because the nucleotide and amino acid sequence databases have grown exponentially since the articulation of that policy. Further, Applicant's claims are not limited to ten nucleotide sequences. The claims recite amino acid sequences and because of codon degeneracy encompass potentially tens of thousands of different polynucleotides having different sequences.

The requirement is still deemed proper and is therefore made FINAL.

5) Claims 1 to 7, 9, 11, 13, 15 to 17, 19, 22 and 26 to 28 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

"Since the decisions in In re Weber **,198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, In re Harnish , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); Ex Parte Hozumi , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

The twenty three different amino acid sequences recited in claim 1 do not have unity of invention because they lack a common utility that is based upon a shared feature or combination of features lacking from the prior art.

M.P.E.P. 2173.05(h) states that "when the Markush group occurs in a claim reciting a process or a combination **(not a single compound)**, it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function **in the claimed relationship**, and it is clear from their very nature or from the prior art that all of them possess this property". It further states that "[w]here a Markush expression is applied only to a portion of a chemical compound, **the propriety of the grouping is determined by a consideration of the compound as a whole**, and does not depend on there being a community of properties in the members of the Markush expression" (emphasis added). The instant claims recite an improper Markush group because they refer to six different individual amino acid sequences which do not reflect a single inventive concept. Correction is required.

6) Claims 3 to 7, 13, 15, 19, 22 and 26 to 28 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. A properly dependent claim can not conceivably be infringed without infringing any of the claims from which it depends. These claims are not properly dependent because claim 3, for example, can be infringed by an isolated polynucleotide that does not infringe the isolated polypeptide of claim 1, from which claim 3 depends. The method of claim 13 is improperly dependent from claim 11

because it neither makes nor uses the isolated polynucleotide of claim 11. See M.P.E.P. 608.01(n)III. Correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7) Claims 1 to 7, 9, 11, 13, 15 to 17, 19, 22 and 26 to 28 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a putative G protein-coupled receptor protein identified therein as "GCREC-1", and the protein encoded thereby. The instant application does not disclose a credible biological role of this protein or its significance, beyond the fact that it is structurally related to proteins which are known in the art to be members of the G protein-coupled receptor family. The "BACKGROUND" section of the instant specification indicates that different members of the G protein-coupled receptor family receptor family bind to a variety of different chemical compounds that mediate significantly different physiological processes in different types of cells. The instant specification does not identify any ligand for a receptor of the instant invention nor does it identify a specific physiological process which one could reasonably associate with that receptor in light of the evidence of record. To be patentable, an invention must be useful in currently available form. Because the instant specification does not disclose the identity of at least one ligand for a receptor of the instant invention or provide a reasonable basis to support a conclusion that this protein is involved in at least one specific physiological process which one would wish to modulate for clinical effect, the

claimed nucleic acid encoding that protein is not useful without further research and inventive contribution.

It is clear from the instant specification that a protein comprising the amino acid sequence presented in SEQ ID NO:1 of the instant application is what is termed an "orphan G protein-coupled receptor" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein and a polynucleotide encoding it may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", " [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to

engross what may prove to be a broad field", and "a patent is not a hunting license", " [i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to an isolated polynucleotide encoding a protein of as yet undetermined function or biological significance and the protein encoded thereby. There is no evidence of record that would support a conclusion the a protein of the instant invention is causally associated with any one or more of the plurality of disorders that are listed on pages 38 to 40, 53 and 54 of the instant specification. Until some actual and specific significance can be attributed to a protein comprising the amino acid sequence presented in SEQ ID NO:1 of the instant application, or the gene encoding it, the instant invention is incomplete. The protein encoded by a DNA of the instant invention is a compound known to be structurally analogous to proteins which are known in the art as G protein-coupled receptors. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a nucleic acid or protein of the instant invention in the identification of substances which inhibit or induce its activity or expression is clearly to use it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for to a protein comprising the amino acid sequence presented in SEQ ID NO:1 then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8) Claims 1 to 7, 9, 11, 13, 15 to 17, 19, 22 and 26 to 28 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

9) Claims 1, 3, 6, 7, 9, 11, 13, 15, 16, 19, 22, 26 and 28 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain an adequate written description that genus of molecules encompassed by the limitations "encoding" "a naturally occurring polypeptide comprising an amino acid sequence at least 90% identical to" "SEQ ID NO:1" or "a naturally occurring polynucleotide comprising a polynucleotide sequence at least 90% identical to a polynucleotide sequence" of SEQ ID NO:9. The vast majority of nucleic acid molecules which meet the structural limitation "at least 90% identical" would not be expected to meet the functional limitation of "naturally occurring" and the instant specification does not identify those material features which distinguish a polynucleotide which meets only the structural limitations of these claims from one which meets both the structural and functional limitations recited therein. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d

1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Because the instant specification does not identify that structural feature or combination of features which distinguish a naturally occurring variant of the disclosed protein or claimed nucleic acid from one which has been intentionally modified, the specification fails to provide a precise description of the claimed genus of nucleic acids encompassed by the limitation “encoding a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to SEQ ID NO:1" “by structure, formula, chemical name, or physical properties” as required by the first paragraph of 35 U.S.C. § 112.

10) Claims 19, 22, 26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the claimed method without first making a substantial inventive contribution.

Claims 19, 22 and 26 are drawn to assays, each of which requires one to detect an "activity" of a "GCREC" polypeptide of the instant invention. The instant specification, however, fails to identify even a single assayable activity that has been attributed to that polypeptide. It is well known in the art that a compound that binds to a G protein-coupled receptor does not necessarily enhance or inhibit the activity of that protein. Therefore, to practice the claimed assay, one is first required to identify one or more compounds that bind to a receptor polypeptide of the instant invention and then to determine if any of those identified compounds effect some physiological parameter in a cell expressing a "GCREC-1" polypeptide without effecting that parameter in an otherwise identical cell lacking that polypeptide. Given the diverse nature of compounds which agonize and antagonize G protein-coupled receptors and the plurality of different physiological process effected by those receptors, one does not have a reasonable expectation of identifying an assayable activity for a "GCREC-1" polypeptide of the instant invention without the need for a substantial amount of undue experimentation.

Further, to practice the method of claim 28 would require the practitioner to establish some relationship between a toxic reaction to a compound and the expression level of a polynucleotide encoding a "GCREC-1" polypeptide of the instant invention, because the instant specification has failed to credibly disclose such a relationship. One does not have a reasonable expectation that a test compound is toxic simply

because it effects the level of expression of a gene encoding a "GCREC-1" polypeptide of the instant invention. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

> "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed method without first making a substantial inventive contribution.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11) Claims 3 to 7, 9, 13, 15 to 17, to 19, 22, 26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11.1) Claims 3 to 7, 9, 16, 17, 19, 25 and 26 are vague and indefinite because there is no antecedent basis for "a polypeptide of claim 1". Claim 1 is directed to "an isolated polypeptide". These claims are confusing because it is unclear, for example, if

the Isolated polynucleotide of claim 3 is require to encode an "isolated" polypeptide of claim 1.

11.2) Claims 6 and 7 are vague and indefinite because there is no antecedent basis for "a polynucleotide of claim 3".

11.3) Claims 13 to 15 and 28 are vague and indefinite because there is no antecedent basis for "a polynucleotide of claim 11".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

35 U.S.C. § 119(e)(1) states that:

> An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the
> same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application. No application shall be entitled to the benefit of an earlier filed provisional application under this subsection unless an amendment containing the specific reference to the earlier filed provisional application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this subsection. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this subsection during the pendency of the application.

12) Claims 1 to 7, 9, 11, 13, 15 to 17, 19, 22 and 26 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by the Takasaki et al. publication (B.B.R.C. 274(2):316-322, 02 Aug. 2000). Takasaki et al. provided a written description of the claimed invention. The amino acid sequence identified as "PSECO146" in Figure 1 of

the Takasaki et al. publication is identical to the amino acid sequence presented in SEQ ID NO:1 of the instant application. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 119(e) from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the now claimed invention. Because the instant application does not meet the requirements of 35 U.S.C. § 112, first paragraph, for those reasons given above and it is a divisional of application Serial Number 60/193,051, the prior application also does not meet those requirements and, therefore, is unavailable under 35 U.S.C. § 119(e).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brunmback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
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